UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In the Matter of:	**)**	
	)	
REQUEST TO REDUCE PRE-HARVEST	**)**	**Docket No. EPA-HQ-OPP-2007-0181**
INTERVAL FOR EBDC FUNGICIDES	**)**	
ON POTATOES	**)**	

ORDER ON EPA'S MOTION FOR CLARIFICATION AND RECONSIDERATION OF ORDER REGARDING SCOPE OF HEARING

I. Procedural Background

The subject matter of this action has a rather long history:

For some sixty years, since 1948, pesticides with the active ingredient of ethylene bisdithiocarbamates (EBDCs) have been registered under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136 *et seq*. (FIFRA). In 1977, the United States Environmental Protection Agency ("Agency" or "EPA") initiated a "Rebuttable Presumption Against Registration and Continued Registration of Pesticide Products Containing EBDCs," *i.e*. a "Special Review" of the risks and benefits of such products. Such Special Review was undertaken by the Agency based upon evidence suggesting that EBDCs and ethylenethiourea (ETU), a common contaminant, metabolite, and degradation product of these pesticides, posed three potential risks to humans and/or the environment: carcinogenicity, developmental toxicity, and acute toxicity to aquatic organisms. Three additional areas of concern were identified as thyroid toxicity, mutagenicity, and skin sensitization. 42 Fed. Reg. 40617 (Aug. 10, 1977). Such Special Review concluded after five years, in 1982, at which time the Agency required implementation of certain risk reduction measures, such a labeling modification, to prevent unreasonable adverse effects pending development of additional data needed to better assess the risks. 47 Fed. Reg. 47669 (Oct. 27, 1982).

Five years later, on July 17, 1987, EPA issued a *second* Notice of Initiation of Special Review of EBDC pesticides because of its continued concern over carcinogenic, developmental, and thyroid effects caused by ETUs. 52 Fed. Reg. 27172 (1987). The result of such second Special Review was that on March 2, 1992, EPA published a Notice of Intent to Cancel ("NOIC") the FIFRA registrations of those pesticide products containing EBDCs. 57 Fed. Reg. 7484 (Mar. 2, 1992). EPA announced in the NOIC that, based upon a risk/benefit analysis, it had determined that the continued use of pesticides containing EBDCs would result in unreasonable adverse effects to humans and the environment *unless* their labeling was again modified to comply with certain terms and conditions further limiting their use. Such terms and conditions included deleting an indication that the products may be used at all on certain crops

(such as apricots, carrots, celery, collards, mustard greens, nectarines, peaches, rhubarb, spinach, succulent beans, and turnips) and imposing additional restrictions on use in regard to others, such as potatoes. As to potatoes in particular, the restrictions on use proposed by the NOIC included a maximum application rate, a maximum number of applications per season, an application interval, and a minimum pre-harvest interval ("PHI"), which is the number of days between the last application of a pesticide and when the crop can be harvested. The NOIC required that the PHI for potatoes be at least 14 days, except that in nine states, the PHI was permitted to be only three days on the basis of data indicating that the late blight disease can cause significant yield losses in those states. Three months later, although the NOIC provided an opportunity for a hearing, the Agency and the registrants (pesticide manufacturers) reached a settlement ("1992 Order"), including an agreement to amend labels to require a 3-day PHI in 13 states and a 14-day PHI in the other states. *American Food Security Coalition*, FIFRA Docket No. 646 *et al.*, 1992 EPA ALJ LEXIS 862 (June 16, 1992).

Four years after that, on December 26, 1996, the EBDC/ETU Task Force ("Task Force" or "applicant"), representing certain registrants of EBDCs, submitted a request to modify the NOIC to reduce the PHI to three days in other states to address the spread of the late blight disease in potatoes. *See*, 72 Fed. Reg. 37771, 37772 (Notice of Hearing on Request to Reduce Pre-harvest Interval (PHI) for EBDC Fungicides on Potatoes, July 11, 2007). Its request apparently not having been granted by the Agency after a pendency of almost seven years, on August 25, 2003, the Task Force took a different tact and submitted applications to amend the registrations of EBDC-containing products, requesting therein that the NOIC be modified and that the Agency initiate a hearing to allow the 3-day PHI on potatoes in all states.[1]

During the EBDC reregistration process, the Agency evaluated the Task Force's request for a reduction of the PHI to 3 days nationwide, and "determined that the exposure that would result from a nationwide 3-day PHI for potatoes would be safe under the FFDCA [Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*] reasonable certainty of no harm standard." 72 Fed. Reg. at 37773. On December 28, 2005, the Reregistration Eligibility Decisions ("REDs") for the EBDC-containing fungicides Mancozeb, Metiram, and Maneb were announced by the Agency in the Federal Register, stating that these products are eligible for reregistration, provided that certain risk mitigation measures and required labeling amendments are adopted, after which the Agency will make a final reregistration decision. 70 Fed. Reg. 76828, 76829, 76830 (December 28, 2005). The REDs for Mancozeb, Metiram, and Maneb, which were issued in August and September 2005, noted receipt of the Task Force's request to allow a 3-day PHI in all states, but did not address whether a hearing under 40 C.F.R. Part 164 Subpart D ("Subpart D") was warranted in regard thereto or whether the request would be granted.

[1] Obviously, it works to the financial benefit of EBDC pesticide manufacturers (and others, such as farmers) to have a shorter PHI in that a shorter interval means the pesticide can be applied more often and/or right before harvest decreasing the likelihood of loss of the potatoes to fungal disease.

However, two years later, on July 11, 2007, the EPA Acting Director of the Special Review and Reregistration Division of the Office of Pesticide Programs published in the Federal Register a Notice of Hearing on Request to Reduce PHI for EBDC Fungicides on Potatoes under the authority of Subpart D ("July 11 Notice"). 72 Fed. Reg. 37771 (July 11, 2007). The July 11 Notice announced EPA's determination that the EBDC/ETU Task Force's request for modification of the cancellation order "has merit" and announced the opportunity for a hearing to be held within 40 days of publication of the July 11 Notice, if an interested party requests a hearing. *Id*. The July 11 Notice stated that if no such hearing is requested, then the EPA intends to file a motion requesting accelerated decision in favor of modifying the cancellation order as requested by the Task Force. 72 Fed. Reg. at 37778.

The Natural Resources Defense Counsel ("NRDC") filed a request for hearing on August 10, 2007, raising certain objections to the reduction in the PHI. The Task Force and EPA are "automatically" parties to this proceeding according to the Notice of Hearing. 72 Fed. Reg. at 37778. The National Potato Council ("NPC") was subsequently granted leave to intervene. The Task Force, representing the applicants, and EPA (as well as the NPC) are all in agreement that the PHI should be reduced to 3 days. Therefore, in this proceeding the Task Force is not (or is no longer) "petitioning" EPA for relief and EPA is not "responding" *i.e*. opposing in whole or in part the petition to reduce the PHI. In fact, if the NRDC had not requested a hearing, EPA's determination to reduce the PHI and any motion for accelerated decision thereon would be unopposed and there would be no further case or controversy for adjudication by this Tribunal. Therefore, the parties are aligned in this case with the Task Force, EPA and the NPC on one side and the NRDC on the other.

By Prehearing Order dated September 19, 2007, the parties were directed, *inter alia*, to file their prehearing exchanges containing the information in their possession supporting their respective positions on the issues to be decided at hearing as those issues were identified in EPA's July 11 Notice of Hearing. On October 15, 2007, EPA, the Task Force and NPC jointly moved for an extension of time to file their prehearing exchanges and requested an early prehearing conference to discuss the scope of the hearing, which NRDC opposed. In their Reply, dated October 26, 2007, EPA (joined by the Task Force and NPC) asserted that it had misstated in the Notice of Hearing as one of the issues to be adjudicated in the Subpart D hearing, the question of whether the applicant (the Task Force), through due diligence, could have discovered the substantial new evidence allegedly warranting the PHI now being reduced nationwide prior to issuance of the 1992 NOIC order (the "due diligence" issue). Therefore EPA requested that the September 19 Prehearing Order be amended to delete the request for information as to the "due diligence" issue, set forth in Paragraph 2(C) of the Prehearing Order. The Reply also noted that there was a dispute between NRDC and the other parties as to whether certain risk issues are within the scope of the hearing.

By Order dated October 29, 2007, the request for an early prehearing conference to discuss the scope of issues was denied, NRDC was provided an opportunity to respond to the request to amend the Prehearing Order to remove Paragraph 2(C), and the prehearing exchange schedule was extended. On November 7, 2007, NRDC filed its response.

On November 15, 2007, EPA, the Task Force and NPC filed a Joint Motion to Defer Ruling on its request to modify the Prehearing Order on the basis that EPA intended to publish an Amended Notice of Hearing containing an amended statement of issues and would thereafter file a motion to amend the Prehearing Order to conform it with the revised issues listed therein. On November 19, 2007, NRDC opposed the Joint Motion to Defer Ruling. On December 3, 2007, an Order was issued granting the Joint Motion to Defer Ruling and suspending the deadlines for the Prehearing Exchange until further notice.

On December 12, 2007, the EPA's "Notice of Hearing Concerning a Request to Reduce the Pre-Harvest Interval for EBDC Fungicides on Potatoes; Amendment to Statement of Issues" ("December 12 Notice") was published in the Federal Register. 72 Fed. Reg. 70586. In addition, on December 12, EPA, joined by the Task Force and NPC, submitted a document ("December 12 Memo") which was in part a reply in support of their October 26 request to delete Paragraph 2(C) from the Prehearing Order, and in part a broader memorandum of law as to the limitation of issues for hearing. The December 12 Memo argued that the issues listed in the July 11 Notice of Hearing, as amended by those listed in the December 12 Notice, are the only issues to be adjudicated in the hearing.

On December 18, 2007, NRDC submitted a Response to the December 12 Memo ("December 18 Response"), accompanied by a motion for leave to file the Response, requesting that this Tribunal disregard the Amended Notice of Hearing and direct the prehearing exchanges to proceed under the original Notice of Hearing. On December 20, EPA filed an opposition to NRDC's December 18 Response.

An Order Regarding Scope of Hearing was issued on January 16, 2008 ("January 16 Order"), denying the October 26 request to delete Paragraph 2(C) from the Prehearing Order, denying the December 12 request to limit the issues for hearing to the issues listed in the December 12 Amended Notice of Hearing, denying the December 12 request to amend the Pre-Hearing Order, and denying the NRDC's request to disregard the December 12 Amended Notice of Hearing. The Pre-Hearing Exchange has not yet been rescheduled, as EPA has in its various filings further challenged the scope of the Pre-Hearing Order, and on January 25, 2008, EPA filed a Request to Defer Schedule in which EPA stated its intention to file a motion for reconsideration or clarification of the January 16 Order.

On February 19, 2008, EPA filed a Motion for Clarification and Reconsideration of the January 16 Order ("Motion"), asserting that the January 16 Order changes the nature and scope of a Subpart D hearing to a "registration-eligibility" action, which is inconsistent with the statutory framework and which would be enormously resource-intensive for EPA. On March 7, 2008, NRDC filed an Opposition to the Motion, and on March 17, EPA filed a Reply thereto. Upon being granted permission to do so, NRDC filed a Surreply on March 28. On April 4, EPA filed a "Reply to NRDC's March 28, 2008 Surreply to EPA's Motion for Clarification and

Reconsideration of the January 16 Order" ("April 4 Submittal"). [2]

II. The Notices of Hearing

The July 11 (original) Notice of Hearing issued by EPA listed the issues to be adjudicated in this proceeding as follows:

> 1. *Issues of fact:* The issues of fact to be adjudicated are:
> (i) What is the current status (nationwide) of late blight on potatoes?
> (ii) Has the occurrence of late blight changed since the initial cancellation order issued in 1992?
> (iii) Are EBDCs necessary to respond to late blight?
> (iv) What are the dietary risks associated with EBDC use on potatoes?
> 2. *Issues of law:* The issues of law to be adjudicated are:
> (i) Has substantial new evidence been presented pertaining to the request to reduce the nationwide PHI on potatoes to 3 days?
> (ii) If it is substantial new evidence, could the applicant, through due diligence, have discovered this information prior to issuance of the cancellation order?
> (iii) Does the 3-day PHI meet the FIFRA 2(bb) standard?

The Amended Notice of Hearing issued on December 12 states that the July 11, 2007 Notice of Hearing "incorrectly identified an issue of law to be adjudicated by the Court," namely that of "due diligence" listed as Issue of Law (ii), and "did not provide a sufficiently clear explanation of the scope of the issues to be considered in the hearing." 72 Fed. Reg. 70586. The Amended Notice then continues as follows:

> In light of the two issues stated above, EPA is amending the Statement of Issues by consolidating the issues of fact and law into the two relevant questions that must be determined by the ALJ consistent with 40 C.F.R. 164.132 and the 1992 cancellation action. EPA believes the amended statement of issues provides necessary clarifications that will allow for a more efficient and effective hearing.

Id. Accordingly, EPA amended the issues of fact and law listed in the July 11 Notice with the following:

> 1. Is there substantial new evidence not considered in the 1992 cancellation that relates to whether the dietary risks associated with nationwide use of EBDCs on potatoes with a 3-day PHI satisfy the relevant statutory standard for registration under FIFRA? For the purposes of this hearing, the relevant portion of the FIFRA standard for registration is

[2] EPA did not include a motion for leave to file its April 4 Reply to the Sur-Reply. However, in the circumstances at hand, it is considered herein.

whether the human dietary risk meets the safety standard in section 408(b)(2) of FFDCA [Federal Food, Drug and Cosmetic Act].

2. Does the substantial new evidence with respect to dietary risk require the modification of the existing cancellation order, i.e., does it support a finding that the dietary risks associated with nationwide use of EBDCs on potatoes with a 3-day PHI satisfy the relevant statutory standard for registration under FIFRA? In other words, do the residues that result from EBDCs on potatoes meet the safety standard in Section 408(b)(2) of FIFRA?

Id.

III. Requests in EPA's Current Motion for Clarification/Reconsideration

In its pending Motion for Clarification and Reconsideration of the January 16 Order, EPA requests that the January 16 Order be *clarified* to hold that:

(1) only dietary issues relevant to the dietary risks that formed the basis of the earlier cancellation order are relevant to this proceeding;

(2) this Tribunal will only make findings and recommendations as to the narrow issue of substantial new evidence and the impact of that evidence on the earlier cancellation decision, and not whether EBDC pesticides meet the standard for registration;

(3) the hearing is limited to the narrow issue of whether the PHI should be reduced to three days for potatoes, and not any other registration issue; and

(4) the only possible outcomes of the proceeding are either that EPA is permitted to reconsider the application to reduce the potato PHI to three days, or that the earlier cancellation order must remain in effect and the application to reduce the PHI to three days may not be considered.

Motion at 3(hereinafter referenced respectively as Clarification Issues 1, 2, 3 and 4). In addition, or in the alternative, EPA requests *reconsideration* of the January 16 Order, seeking rulings that:

(1) neither the necessity for EBDC pesticides nor the spread of late blight are relevant to the findings necessary in this Subpart D hearing;

(2) the scope of the Subpart D hearing may not be expanded to include additional dietary risks, or any non-dietary risks, that were not part of the initial cancellation proceeding;

(3) the [Amended] Notice of Hearing sets forth the only issues to be adjudicated in this

Subpart D hearing; and

(4) the Administrator's finding of "due diligence" is not an issue for this Subpart D hearing.

Motion at 3-4 (hereinafter referenced respectively as Reconsideration Issues 1, 2, 3 and 4).

IV. Discussion

There is no provision in Subpart D for reconsideration of an interlocutory order, so case law from Federal court is useful as guidance. *Lazarus, Inc*., 7 E.A.D. 318, 330 n. 25, 1997 EPA ALJ LEXIS 27 (EAB 1997)(where EPA Rules do not address a particular procedure, federal case law may provide guidance). A motion for reconsideration is not an opportunity to re-argue a case. *Sault Ste. Marie Tribe of Chippewa Indians v. Engler*, 146 F.3d 367, 374 (6th Cir. 1998). Reconsideration is appropriate only if the movant presents newly discovered evidence, the court committed clear error or the decision was manifestly unjust, or if there is an intervening change in controlling law. *School Dist. No. 1J, Multnomah County v. A C and S, Inc.*, 5 F.3d 1255, 1263 (9th Cir. 1993), *cert. denied*, 512 U.S. 1236 (1994); *Southern Timber Products*, 3 E.A.D. 880, 888-89 (J.O. 1992).

EPA has not claimed or shown any newly discovered evidence or intervening change in controlling law in regard to the conclusions reached in the January 16 Order, but in its Reply (at 3) asserts that the standard of "clear error" is appropriate, referring to 40 C.F.R. § 164.110(c), and argues that it has met that standard.

A. Issues for Hearing Limited to Reduction of PHI to 3 Days Nationwide (Clarification Issues 2, 3 and 4)

There is no dispute that the hearing in this matter is limited to the question of whether to reduce the PHI nationwide to three days for potatoes, which is to be determined by addressing the issues set forth in 40 C.F.R. § 164.132(a), and that this hearing does not address the general question of whether EBDCs should continue to be registered under FIFRA. As the NRDC states in its Opposition (at 4-5), it merely opposes the Task Force's request to reverse the prior cancellation order only in respect to reduction in the PHI to 3 days nationwide. It is also undisputed that the only possible outcomes of this proceeding are a conclusion either that substantial new evidence exists that requires reversal or modification of the 1992 Order with regard to the PHI, or that the earlier cancellation order must remain in effect and the application to reduce the PHI nationwide to three days may not be considered. *See*, Opposition at 5. The applicants' registrations of pesticides with EBDCs as they now exist are not at risk or at issue.

However, the July 11 Notice included as an issue of fact for hearing "What are the dietary risks associated with EBDC use on potatoes?" Arguably this question as written could encompass consideration of any and all dietary risks associated with EBDCs, whether raised by

the parties or not, or whether relevant to the PHI or not, and is of a type which would normally be addressed in the registration and reregistration process rather than in a hearing. Therefore, clarification is appropriate to the extent that the January 16 Order did not sufficiently indicate that the hearing in this matter will only address the question of whether the PHI should be reduced nationwide to three days for potatoes, based on adjudication of the issues stated in 40 C.F.R. § 164.132(a), and that the outcome of this matter is a conclusion either that substantial new evidence exists that requires reversal or modification of the 1992 Order or that the earlier cancellation order must remain in effect and the application to reduce the PHI nationwide to three days may not be considered. Accordingly, Complainant's Motion for Clarification is granted as to Clarification Issues (2), (3) and (4).

B. Standard for Registration and Additional Dietary Risks (Clarification Issue 1 and Reconsideration Issue 2)

1. EPA's Arguments

EPA reiterates its position, stated in its submissions filed prior to the January 16 Order, that the hearing in this case should be limited to addressing the three dietary issues (carcinogenicity, developmental effects and thyroid effects) listed in the NOIC issued in 1992, some sixteen years ago. As background for its arguments, EPA describes its pesticide registration, cancellation, special review and reregistration processes. In the registration and reregistration processes, EPA states it performs a "broad review of every potential risk issue" and does not offer any opportunity for hearing, except for applicants aggrieved by EPA's proposal to deny an application. Motion at 10, 19, 29; Reply at 4. There are only limited opportunities for public participation in such processes, namely opportunities to comment on certain registration applications, tolerance actions, and reregistration-related documents. Motion at 10, 19-20. However, it says that an interested person may petition the Agency to cancel the registration or to initiate or comment on a Special Review of a pesticide, which may result in a NOIC. Motion at 11, 13-14. After a NOIC is issued, a hearing is provided under 40 C.F.R. Part 164 Subpart B, but is generally limited to issues in the Notice of Intent to Cancel. Motion at 16-17. In contrast with these procedures, EPA argues that Subpart D only provides limited jurisdiction on those issues in the initial cancellation hearing "that affected the prior order," since the Subpart D hearing is for the reconsideration of the prior order. Motion at 25-26. EPA urges that a Subpart D hearing may not be expanded to include a full inquiry on registration, and cannot include consideration of dietary risks that were not included in the original cancellation proceeding.

EPA also asserts that *after* the Subpart D hearing ends and a decision is issued, EPA staff will then decide whether the 3-day PHI meets the FIFRA standard for registration "based on all available information on risks and benefits, as appropriate." In support, EPA cites to the Administrator's statement on appeal of a decision in a Subpart D proceeding that "[t]he outcome of this proceeding should be and is a determination of whether the facts presented 'require modification of the 1972 Order . . . in accordance with FIFRA,' rather than the ultimate question

of whether the particular applications meet all the requirements for registration of FIFRA," although "a modification of the 1972 Order . .. as a result of this proceeding, determines many of the ultimate facts relating to registration as well." *Applications to Register Sodium Cyanide for Use in the M-44 Device to Control Predators*, 1 E.A.D. 44, 1975 EPA App. LEXIS 9, *16-18 (Adm'r 1975). EPA also cites to the Notice of Hearing in that proceeding, in which EPA stated that "those portions of the substantive rationale or the existing order concerning which the petitioner did not submit substantial new evidence are assumed to be correct," and therefore "the scope of any Subpart D hearing is intrinsically narrower than the proceeding which was held or could have been held concerning the order to be reconsidered." 52 Fed. Reg. 4963, 4965 (1987). EPA argues that if NRDC is allowed to present other dietary risks (such as reproductive or endocrine disruption) in this Subpart D hearing, then this proceeding will be transformed to one "focusing on the much broader issue of whether the EBDC application meets the FIFRA standard for registration." Motion at 28.

EPA additionally takes issue with the following statement in the January 16 Order (at 12): "To initiate another Special Review and cancellation process based on evidence of these [two] additional [dietary] risks would take far more Agency resources and time than considering them in a Subpart D proceeding." EPA asserts that this statement "both ignores the fact that the Agency has done more recent analyses of the EBDCs since the earlier cancellation action and assumes that the Subpart D hearing is an appropriate forum for broad consideration of whether a product meets the standard for registration." Motion at 29. EPA points out that it conducted a thorough examination of all data submitted and "all other available data found by the Administrator to be relevant" in the reregistration process, which culminated in the REDs, and that EPA therein "determined that there are no unreasonable adverse effects that result from the use of the EBDC pesticides." Motion at 30. Moreover, after the hearing in this proceeding, EPA staff will make the final registration determination regarding any other potential risks. Reply at 6.

EPA asserts that NRDC has alternative avenues of relief, by petitioning to cancel the EBDC pesticide registration, and that EPA's decision thereon may be challenged in Federal court. Motion at 32. EPA expresses concern that the January 16 Order could provide a basis for a party to argue that *any* issue could be raised in a Subpart D hearing. Motion at 32. EPA urges that the "cumulative effect of all past and present uses" clause of 40 C.F.R. §164.132(a) is limited to considering whether reducing the PHI will result in an unacceptable dietary risk, which must consider the "impact of any change in exposure resulting from the proposed change in the PHI for potatoes on the cumulative effect on dietary risks of all uses of EBDCs." Reply at 6.

2. NRDC's Arguments

In its Opposition NRDC asserts that EPA's Motion improperly attempts to relitigate issues already briefed and decided without providing new authority in support, and to limit the scope of the hearing, which would unlawfully exempt this proceeding from critical provisions of

FIFRA and the issues for Subpart D hearings set out at 40 C.F.R. §164.132. In addition, NRDC points out that the Task Force, not EPA, has the burden of proof, so any obligation EPA assumes in support of the Task Force is self-imposed. Moreover, not all relevant matters in this proceeding must be adjudicated after a hearing, as there are opportunities for stipulations, motions practice, and other mechanisms to narrow the issues. Some Subpart D hearings, however, do involve dozens of witnesses, hundreds of exhibits and months of testimony, NRDC points out. Citing to case law setting standards for reconsideration in Federal court, NRDC asserts that EPA, setting out arguments it made or previously could have made, has not met those standards.

NRDC asserts that the only new argument EPA makes is that the January 16 Order will convert this proceeding into a "registration-eligilibity" action. NRDC does not challenge the registration eligibility of EBDCs, or seek cancellation of any EBDC use, but merely opposes the Task Force's request to reverse the prior cancellation order as to the PHI. Sur-Reply at 2. Thus, initiating a cancellation proceeding is not an alternative method of providing the relief NRDC seeks. However, NRDC asserts, consideration of the health and environmental risks and benefits of all uses must be considered to determine whether the reversal of the limitations in the cancellation order is safe. EPA's position, that only the three dietary risks that formed the basis of the 1992 cancellation order are relevant, disregards the plain language of Section 164.132(a) that this Tribunal "shall" take into account "the cumulative effect of all past *and present* uses . . .," NRDC argues, and inappropriately weakens the standard for reversing a cancellation decision. Opposition at 6-7

NRDC further argues that EPA limits the hearing to the issue of whether the cancellation decision would have been resolved differently if new information presented by the *Task Force* - but not any new information presented by any other parties - had been presented in the 1992 cancellation proceeding. Opposition at 9. NRDC argues that there is no support for EPA's position in this regard. NRDC also argues that EPA's position that this proceeding is to determine what would have been heard in the cancellation proceeding had a hearing taken place rather than the settlement, is illogical and forces this Tribunal to wilfully ignore all significant scientific developments since 1992. Opposition at 10-11. Effects of endocrine disruption, NRDC urges, is one such significant development, and is relevant to assessing the "cumulative effect of all past and present uses" of EBDCs. *Id.* at 11.

3. Analysis and Conclusion

Consideration of the two additional dietary risks of reproduction and endocrine disruption presented by NRDC in its request for hearing does not transform this proceeding into one which addresses the broad issue of whether the EBDC application meets the FIFRA standard for registration. A hearing on new evidence as to several dietary risks presented by the applicant would not necessarily be any narrower than a hearing on new evidence as to the same number of dietary risks, half of which are presented by that applicant and half by another party.

EPA's argument that jurisdiction in this proceeding is limited to those issues in the initial 1992 cancellation hearing "that affected the prior order," since the Subpart D hearing is for the reconsideration of the prior order, and thus cannot include consideration of dietary risks that were not included in the cancellation proceeding (Motion at 25-26), is flawed.

The reversal or reconsideration of a cancellation order is not the same as reversal or reconsideration of *particular findings* within a cancellation order. The applicable regulations, at 40 C.F.R. § 164.130-164.132, provide that Subpart D hearings are for reconsideration of a cancellation *order* based upon "substantial new evidence." The Task Force seeks to reverse the *conclusion* in the cancellation order that except for 13 states, the appropriate PHI is 14 days, based on, *inter alia*, new evidence relevant to the *findings* in the cancellation order as to certain dietary risks. NRDC seeks to oppose reversal of that *conclusion*, based on evidence of *other* dietary risks.

In a Subpart D proceeding, the hearing is required to be announced to the public in the Federal Register and is required to be held in accordance with the Administrative Procedure Act ("APA"), 5 U.S.C. § 554. 40 C.F.R. § 164.131(c). Section 554(c) requires that all interested parties shall be given an opportunity for "the submission and consideration of facts . . ." and that a hearing be held in accordance with Sections 556, which provides that "Any oral or documentary evidence may be received" except for that which is "irrelevant, immaterial, or unduly repetitious," and that a party is entitled to present his case or defense by oral or documentary evidence and to submit rebuttal evidence. 5 U.S.C. § 556(d). Thus, a Subpart D proceeding is an adversarial proceeding in which all parties may submit facts and evidence which is relevant and material to the outcome of the case.

A Subpart D proceeding is a case concerning reversal or modification of a cancellation order. To reverse or modify a limitation on use in a cancellation order, substantial new evidence must be shown by an applicant (for use of a pesticide under Section 3 or 18 of FIFRA) in support of such reversal or modification. 40 C.F.R. § 164.130-164.132. Other parties to the proceeding may submit evidence that is relevant and material to their case, that is, their opposition to the relief requested (reversal or modification of the cancellation order). The applicant is limited to presenting evidence which is relevant and material to mitigation or elimination of the risks found in the cancellation order, because mitigation or elimination of *other* risks would not mitigate or eliminate the risks found in the cancellation order. However, there is no such limitation on other parties either in Subpart D or in the APA. Evidence that is relevant and material to the case, that is, whether to reverse or modify the cancellation order as the applicant requests, may include evidence of risks which were not found in the cancellation order, and which show that the applicant's requested use would not be safe under the applicable standard. This conclusion is consistent with the broad factor that "shall" be taken into account: "the *cumulative effect* of *all* past *and present uses*, including the requested use, and uses which may reasonably be anticipated . . . ." 40 C.F.R. § 164.132(a)(italics added). This conclusion is not inconsistent with the Administrator's statement that a Subpart D proceeding "is a determination of whether the facts presented require modification of the 1972 Order." *Applications to Register Sodium Cyanide for Use in the M-44 Device to Control Predators*, 1 E.A.D. 44, 1975 EPA App. LEXIS 9, *16-18

(Adm'r 1975).

To illustrate this point, take for example the simple hypothetical situation where a particular pesticide use - on turnips in winter - is cancelled due to a dietary risk that such use can cause blindness. Ten years later, an applicant requests modification of the cancellation order and presents new scientific evidence to show that use of the pesticide in winter has been proven not to cause blindness and EPA agrees to the modification based on the new evidence and issues a Notice of Hearing thereon. In response to the Notice of Hearing, a person opposes modification of the cancellation order, perhaps even agreeing that use of the pesticide in winter does not cause blindness, but asserting that newly discovered evidence shows the pesticide use on turnips in winter causes a significant risk of deafness. In EPA's view, the person would be precluded from presenting that new evidence regarding deafness in the Subpart D proceeding. EPA would suggest that the person instead petition EPA to initiate a cancellation of the pesticide. However, if the existing cancellation order sets sufficient precautions against dietary risks of deafness by not allowing its use at all in winter, there is no basis for initiating a cancellation proceeding.

If no evidence of dietary risks of deafness is permitted to be introduced in the Subpart D proceeding, the application for modification of the cancellation order might well be fecklessly approved as unopposed, which may subject the public to a significant risk for deafness. This risk would continue unabated unless a petition for cancellation or special review is received and a NOIC issued. If a cancellation proceeding is then subsequently instituted on the basis that the ALJ- approved pesticide use causes deafness, such a proceeding would only blatantly demonstrate the desultory nature of the prior constricted Subpart D proceeding and this Tribunal's imprimatur resulting therefrom. Furthermore, EPA's suggestion that *after* the Subpart D hearing ends and a decision is issued, EPA staff will *then* decide whether the 3-day PHI meets the FIFRA standard for registration "based on all available information on risks and benefits, as appropriate" seems a hollow promise at best since EPA has *already* "determined that the exposure that would result from a nationwide 3-day PHI for potatoes would be safe under the FFDCA reasonable certainty of no harm standard," (Motion at 20-21), that the request for modification "has merit," and that EPA intends to grant it, and that EPA does not need any additional data on any other dietary risks from the Subpart D process. Under the constricted hearing process it supports, the Agency would not receive from that process any new evidence warranting reconsideration of its announced position.

EPA's citation to a 1987 Notice of Hearing in which EPA stated that "those portions of the substantive rationale or the existing order concerning which the petitioner did not submit substantial new evidence are assumed to be correct," and therefore "the scope of any Subpart D hearing is intrinsically narrower than the proceeding which was held or could have been held concerning the order to be reconsidered" (52 Fed. Reg. 4963, 4965 (1987)), does not support the exclusion of evidence of the additional dietary risks referenced by NRDC in its request for hearing. First, the 1987 Notice of Hearing is not any more persuasive than EPA's Notice of Hearing in the present case - a notice which it took almost eleven (11) years to write and issue (from the 1996 Request filing until 2007) and then still had to amend due to erroneous misstatements made therein. Further, an *assumption* may be rebuttable, and finally, the Notice

does not address a situation of a party other than the applicant or EPA submitting evidence in opposition to the proposed reconsideration.

EPA appears to downplay the importance of evidence of other dietary risks in this proceeding on the basis that it recently conducted a thorough examination of "all relevant data submitted," including evaluation of the 14-day and 3-day PHIs as part of the REDs, and that in the REDs, EPA "determined that there are no unreasonable adverse effects that result from the use of the EBDC pesticides" and that "[t]hrough the reregistration process, EPA determined that the exposure that would result from a nationwide 3-day PHI for potatoes would be safe under the FFDCA reasonable certainty of no harm standard." Motion at 20-21, 30; 72 Fed. Reg. at 37774. However, at this point in the proceeding, EPA has not asserted or established that "all relevant data submitted" includes data as to the dietary concerns raised by NRDC. Moreover, if EPA has already thoroughly examined "all relevant data" as to the 3-day PHI and made a determination that it meets the applicable safety standard, and if its request is granted to preclude NRDC from presenting in this proceeding any evidence regarding any issues other than those considered and already resolved in the applicants' favor by EPA, there would appear to be no purpose for the present hearing. A decision made by an Administrative Law Judge under the APA, or a decision by a judge in federal court, is intended to be an independent exercise in judgment, an informed decision made after considered choices. *See e.g.*, *Dickenson v. Zurko*, 527 U.S. 150, 155 (1999)("[T]he Court has stressed the importance of not rubber-stamping agency fact-finding . . . The APA requires meaningful review . . . ."); *Patterson v. General Motors Corp*., 451 U.S. 914 (1981)(Burger, C.J. dissenting)(it is not a proper exercise of this Court's judicial power merely to "rubber stamp" actions of State administrative board).

In sum, EPA has not shown that the January 16 Order's ruling that dietary risks referenced in NRDC's Request for Hearing, dated August 10, 2007, are properly within the scope of the hearing in this matter, involves "clear error" or is "manifestly unjust," nor has EPA shown any other reason sufficient for reconsideration of the ruling. Accordingly, EPA's request for reconsideration to hold that the scope of the Subpart D hearing may not be expanded to include additional dietary risks, or any non-dietary risks, that were not part of the initial cancellation proceeding, is denied. In addition, EPA's request to clarify that "only dietary issues relevant to the dietary risks that formed the basis of the earlier cancellation order are relevant to this proceeding" (Clarification Issue 1) is denied.

C. Necessity for EBDCs and Spread of Late Blight (Reconsideration Issue 1)

1. EPA's Arguments

EPA requests this Tribunal reconsider the January 16 Order and conclude that neither the necessity for EBDC pesticides nor the spread of late blight are relevant to the findings necessary in this Subpart D hearing.

A pesticide may be registered, under Section 3(c)(5)(C) of FIFRA (7 U.S.C. §

136a(c)(5)(C)), only if it will perform its intended function without "unreasonable adverse effects on the environment," a phrase which is defined in the two prongs of Section 2(bb) of FIFRA, 7 U.S.C. § 136(bb), as not causing either: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with" the standard of Section 408(b)(2)(A)(ii) of the Federal Food Drug and Cosmetic Act (FFDCA), that is, that it has been determined to be "safe" in that there is "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue."

EPA argues that benefits (the first prong) may not be used to balance against dietary risks (the second prong). Motion at 33. EPA points out that "[i]f a pesticide poses meaningful dietary risks, it fails the second prong of Section 2(bb) and the issue of whether it passes the first prong becomes irrelevant, because the pesticide may not be registered no matter what the outcome of the cost-benefit deliberation." Motion at 34. EPA asserts that the standard of FFDCA 408 is a "new risk-only standard." *Id.* EPA cites to a provision of Section 3(c)(5) of FIFRA, which sets out the factors for registration of a pesticide, and that "[t]he Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide." Motion at 34. EPA reasons that "if a pesticide poses essentially no risk . . . , requiring any amount of vigor in a benefits showing is equivalent to demanding that the pesticide's essentiality be demonstrated." Motion at 34-35. Based on these premises, EPA concludes that where there are "no meaningful risks," benefits (under the first prong) cannot be considered. Motion at 34. On the other hand, EPA states that if there are "meaningful non-dietary risks" (such as risks to pesticide applicators, spray drift), then consideration of benefits is relevant, because they are both factors to be balanced under the first prong of FIFRA Section 2(bb). Motion at 35, Reply at 4-5, n. 4. However, because non-dietary risks were not part of the original cancellation action, benefits are not relevant in this proceeding it suggests. Motion at 35; Reply at 5.

EPA further asserts that it has already determined that the EBDC tolerances met the standard of FFDCA Section 408, and thereby met FIFRA 2(bb)(2). Therefore, EPA concludes, issues as to benefits, including the necessity for EBDC pesticides and the spread of late blight, are not relevant to the outcome of this proceeding. Motion at 35.

2. NRDC's Arguments

Contrary to EPA's position, NRDC reemphasizes that both prongs of the standard in FIFRA section 2(bb), including the "economic, social and environmental costs and benefits," must be satisfied before a cancellation order is reversed by new evidence. Because issuance of a cancellation order is based on a finding that a pesticide use *will cause* unreasonable adverse effects on the environment, defined by both prongs of FIFRA Section 2(bb), reversal of a cancellation order requires a finding that permitting use *will not cause* unreasonable adverse effects on the environment under both prongs of FIFRA Section 2(bb). The issues of whether alternative fungicides adequately control late blight, and whether late blight has spread, are

relevant to that standard and the issue of "essentiality" is off point, NRDC argues. Opposition at 13.

3. Analysis and Conclusion

EPA in its July 11 Notice included in its list of issues of fact to be adjudicated in this proceeding the following: (i) What is the current status (nationwide) of late blight on potatoes? (ii) Has the occurrence of late blight changed since the initial cancellation order issued in 1992? and (iii) Are EBDCs necessary to respond to late blight? The January 16 Order held that these issues were not shown to be immaterial or irrelevant to the applicable standard under FIFRA Section 2(bb).

Section 3(c)(5)(C) of FIFRA, 7 U.S.C. § 136a(c)(5)(C), provides that the "Administrator shall register a pesticide if the Administrator determines that . . . it will perform its intended function without unreasonable adverse effects on the environment . . . ." The term "unreasonable adverse effects on the environment" is defined in Section 2(bb) of FIFRA, as:

> (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental *costs and benefits* of the use of any pesticide, or
> (2) a human *dietary risk* from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21 [the Federal Food, Drug and Cosmetic Act (FFDCA)].

7 U.S.C. § 136(bb)(italics added). The Food Quality Protection Act of 1996 added the second prong to the definition above.

In turn, Section 346a of Title 21 of FFDCA, provides:

> . . . the term "safe," with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is *a reasonable certainty that no harm will result* from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

21 U.S.C. § 408(b)(2)(A)(ii).

Reading these provisions together, EPA asserts that *benefits* may only be balanced against non-dietary costs or risks under the first prong of FIFRA Section 2(bb), and that if there are no "meaningful [dietary and non-dietary costs or] risks of concern," EPA generally grants registration without assessing benefits, because Section 3(c)(5) of FIFRA provides that "[t]he Administrator shall not make any lack of essentiality a criterion for denying registration of any

pesticide."[3] Motion at 7-8. On the other hand, if a pesticide poses "meaningful dietary risks," it fails the second prong of Section 2(bb) and the pesticide may not be registered regardless of the benefits. Motion at 34-35. In this case it states it has already determined that the EBDC tolerances met the standard of FFDCA Section 346a of Title 21 and thereby met the second prong of FIFRA 2(bb)(2). Further, it notes that non-dietary risks were not part of the original cancellation action. Therefore, it states that the benefits of EBDCs, such as its efficacy in terms of responding to late blight, are not relevant in this proceeding because to consider them would in effect be determining their essentiality, which is prohibited. Motion at 35; Reply at 5.

EPA's argument is in error as its conclusion does not logically follow from its premises. First, EPA has not demonstrated that the "lack of essentiality" provision applies to cancellation proceedings. The fact that the same standard for safety applies to both registration and cancellation does not establish that the "lack of essentiality" provision applies to cancellation or reconsideration thereof. In reconsideration of a limitation on use of a pesticide in a cancellation order, the presumption from the cancellation order is that the proposed use has meaningful dietary or non-dietary risks, otherwise it would not be cancelled. If the proposed use has no benefits, or an extremely small incremental increase in benefits, but a relatively large risk if the existing labeling or mitigation requirements are not complied with, then it would be illogical to exclude consideration of benefits from the determination of whether to reconsider the limitation on the proposed use.

Second, it is noted that the "lack of essentiality" provision has applied for decades to the registration of a pesticide,[4] including the time prior to the Food Quality Protection Act of 1996 (FQPA), when dietary risks were weighed against benefits under the first prong of Section 2(bb). *See*, Motion n. 23. Therefore, the "lack of essentiality" provision does not preclude all consideration of benefits. Indeed, EPA does not cite to any authority clearly establishing that the FQPA eliminated consideration of benefits where dietary risks do not exceed the standard.

Third, EPA characterizes "benefits" as "generally focusing on the comparative efficacy and cost-effectiveness of alternatives," and characterizes pesticides which meet the standard of no "unreasonable adverse effects on the environment" under both prongs of FIFRA Section 2(bb) as "*risk-free*," stating that "[t]he Agency would not generally have sufficient efficacy data to be able to determine whether one *risk-free* pesticide were more efficacious than the other in combating late blight, and even if it did . . ., preferring one pesticide to the other in such circumstances would violate the non-essentiality provisions." Motion at 8-9. These characterizations are overly simplified, particularly in the context of pesticide cancellations generally and this case in particular. EPA has not shown that EBDCs are absolutely "risk-free"

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[3] "Lack of essentiality," means that there are other approved pesticides which adequately respond to infestation on the affected crop.

[4] Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516 § 2, 86 Stat. 973, 981 (amending section 3(c)(5)).

at any dosage, and obviously at some dosage, by definition an *overdose*, EBDCs are harmful. "No *unreasonable* risk of harm" does not mean *no* risk of harm. As noted in the Procedural History above, many uses of EBDCs were and are currently cancelled or voluntarily withdrawn due to concerns of dietary and other risks. 72 Fed. Reg. at 37773. As EPA acknowledges, the 1992 NOIC "concluded that the relatively high estimated dietary risk (carcinogenicity, developmental and thyroid effects) outweighed the relatively low benefits of the use of EBDCs on potatoes" but nevertheless "allowed the 3-day PHI in [nine] states because the data on late blight, efficacy of possible alternatives, and residue data allowed EPA to find that the benefits outweighed the risks." Motion at 17-18. EBDC tolerances are considered "safe" only as long as the specified mitigation and labeling requirements are complied with. The issues of benefits raised in this proceeding are not the mere economic advantages of comparative efficacy and whether the pesticide is less expensive than alternatives, but whether EBDCs are needed to combat a serious fungal disease on potatoes and whether effective alternative methods of control exist. If there is some increased risk of harm from reducing the PHI and no significant benefit, then it may be reasonable to conclude that the PHI should not be reduced. Thus, the risks of harm raised by the parties must be weighed against the benefits raised by the parties in this proceeding.

In the January 16 Order, it was held that the three issues listed in EPA's July 11, 2007 Notice of Hearing concerning the status and occurrence of late blight and necessity of EBDCs were not shown to be immaterial or irrelevant to the applicable standard under FIFRA Section 2(bb). EPA has not shown that the ruling involves "clear error" or is "manifestly unjust," nor has EPA shown any other reason sufficient for reconsideration of that ruling.

C. Scope of Hearing set forth in Notice of Hearing is Binding (Reconsideration Issue 3)

1. EPA's Argument

EPA stoutly reiterates its position that the EPA Administrator, through his delegate, the EPA trial staff, delineates the scope of the Subpart D hearing in the Notice of Hearing.[5] In support, EPA argues that the cases cited in the January 16 Order actually support its position rather than the conclusion in the Order. In addition, EPA cites statements of EPA Administrator Thomas in *Application to Modify the Final Suspension Order for Pesticide Products Containing Dinoseb*, 2 E.A.D. 349, FIFRA Docket No. 622, 1987 EPA App. LEXIS 38 (Adm'r 1987). EPA argues that if this Tribunal does not "give effect" to the Notices of Hearing, then the purpose of the notice - to inform the public what action the Agency intends to take - is nullified. Motion at 40.

[5] EPA acknowledges that the original Notice of Hearing it published in regard to this proceeding contained issues that cannot be heard in a Subpart D hearing and had to be corrected through issuance of the amended Notice of Hearing. Motion at 36.

2. Analysis and Conclusion

The Notice of Hearing is given due effect as an announcement by EPA of the opportunity for a hearing, of the issues EPA proposes for hearing, and of the action and position EPA intends to take, with supporting details and information. As such, it is not a limitation on the issues for hearing listed in Subpart D, nor is it a limitation on issues which are encompassed by issues listed in Subpart D and that are raised by another party to the hearing in opposing the relief requested by the applicant in the Subpart D hearing.

EPA's reiteration of arguments and disagreement as to the interpretation of text in administrative decisions does not establish "clear error" or any other standard for reconsideration. The statements of EPA Administrator Thomas in *Application to Modify the Final Suspension Order for Pesticide Products Containing Dinoseb*, 2 E.A.D. 349 are the statements of the Administrator as the *adjudicator* determining the scope of the proceeding in which he was presiding, and furthermore, his statements were made in the context of reconsideration of a suspension of pesticide products, in which he distinguished the scope of risk issues presented therein with "many generic risk issues" which would be subject to full examination in the cancellation proceeding.

The January 16 Order held that the Amended Notice of Hearing has no binding legal effect to authorize the elimination of issues that are properly within the scope of the Subpart D hearing. EPA has not shown that this ruling involves "clear error" or is "manifestly unjust," nor has EPA shown any other reason sufficient for reconsideration of that ruling.

D. Due Diligence (Reconsideration Issue 4)

1. EPA's Argument

EPA reaffirms its belief that the ALJ has no authority to hear and decide issues as to whether a delegate of the Administrator abused his discretion in making a determination as to the due diligence issue. Motion at 41. In support, EPA asserts that the general provision of 40 C.F.R. § 22.4(c)(7), which sets out the ALJ's authority to "hear and decide questions of fact, law or discretion" does not apply to Subpart D proceedings. EPA reiterates that the ALJ's jurisdiction is "very narrow," reiterates its interpretation of the Subpart D regulations, and notes that a federal court may be able to hear a claim of abuse of discretion. Motion at 41-44 and n. 40. EPA argues that the issue of whether "substantial new evidence exists" does not include the issue of whether the evidence could have been made available through the exercise of due diligence at the time of the initial cancellation, asserting that if an item of evidence was in fact available at the time of the cancellation, then it is not "new" whereas "due diligence" focuses on actions the party could have taken to make the evidence available. Motion at 43. Pointing out that the provision in Subpart D setting out the Administrator's duties, 40 C.F.R. § 164.131, refers to "due diligence" and the provision setting out issues for hearing, 40 C.F.R. § 164.32, does not, EPA refers to the presumption of statutory construction that omission of a term in one section

but inclusion in another section is intentional, and the principle that a court is without authority, absent "substantial evidence to the contrary, to add terms or provisions that have been omitted." Motion at 45, citing *Cervantes -Ascensio v. INS*, 326 F.3d 83, 86 (2nd Cir. 2003)(internal quotation omitted).

2. NRDC's Argument

NRDC points out that EPA only repeats arguments it has made in previous filings. NRDC's position is that the issues of whether substantial new evidence exists, and whether it requires reversal of the prior cancellation, require consideration of whether the evidence could have, through exercise of due diligence, been discovered prior to the cancellation proceeding. NRDC reiterates that principles of fairness and due process require that the due diligence issue be adjudicated.

3. Analysis and Conclusion

The authority of ALJs in the general provision of 40 C.F.R. § 22.4(c)(7) to "hear and decide questions of fact, law or discretion" is reflective of the provision in Section 557 of the APA that "[a]ll decisions, including initial, recommended and tentative decisions . . . shall include a statement of – (A) findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law *or discretion* presented on the record." 5 U.S.C. § 557(c)(3)(A) (emphasis added). Subpart D proceedings are subject to Section 554 of the APA, which in turn requires hearings and decisions in accordance with Sections 556 and 557 of the APA.

The lengthy discussion in the January 16 Order concerning the interpretation of 40 C.F.R. § 164.131 and 164.132 and whether the ALJ may consider the "due diligence" issue did implicitly contemplate principles of statutory construction, including the well-known presumption and principle cited in the Motion.[6] The January 16 Order (at 9) stated, "The 'due diligence' issue, that is, whether the evidence could, through exercise of due diligence, have been discovered by the parties prior to the issuance of the final order, may in some cases be relevant to the ALJ's determination of whether 'substantial new evidence' exists and whether it requires reversal or modification of the cancellation order." To illustrate further by way of a simple hypothetical, if certain evidence available at the time of a cancellation order was not known to the pesticide registrant, but upon its request to modify the cancellation order, it presented the evidence, a party opposing the request could assert that the data is not "new" and thus could not meet the standard of "substantial new evidence" on the basis that with exercise of due diligence, the evidence could have been presented at the time of the cancellation proceeding. The issue of whether "substantial new evidence" exists would thus include the issue of "due

[6] *See*, January 16 Order, slip op. at 9 (concluding that "the regulatory text does not preclude the ALJ's consideration of the due diligence issue, albeit the "due diligence" issue is not mentioned in Section 164.132.")

diligence."

EPA's reiterations of arguments made in previous filings, and arguments which could have been made therein, do not meet any standard for reconsideration. EPA has not shown that the denial of the request to delete the "due diligence" issue from the Pre-Hearing Order involves "clear error" or is "manifestly unjust," nor has EPA shown any other reason sufficient for reconsideration of that ruling.

V. EPA's Request to Adjust the Sequence of Presentation

The Pre-Hearing Order issued in this proceeding directed the Task Force and EPA to submit their Pre-hearing Exchanges on or before a certain date, and NRDC to submit its pre-hearing Exchange on or before a subsequent certain date. In its Reply, EPA requests that the sequence of submissions be changed so that the Task Force submits its pre-hearing exchange first, NRDC submits its pre-hearing exchange second, and then EPA submit its pre-hearing exchange third. EPA suggests that the parties have an opportunity to submit rebuttal pre-hearing exchanges afterward. EPA argues that it does not know what evidence NRDC will present, and that once the other parties have submitted their proposed evidence, then EPA will be able to decide whether it is necessary for it to present any evidence at the hearing. Reply at 6-7.

NRDC states that it does not seek any affirmative relief or additional restrictions on EBDC use, but merely challenges EPA decision to reduce the PHI to 3 days nationwide. Sur-Reply at 2. It is logical for the parties requesting the change in the registration to disclose their evidence affirmatively supporting such change first and for EPA to disclose relevant information upon which it based its decision that to support the Task Force's change request with it, NRDC asserts. Further, NRDC argues that rebuttal pre-hearing exchanges would remedy EPA's concern that it does not know what evidence NRDC would present. SurReply at 2-3. NRDC's view is that the requested change in sequence would only complicate the pre-hearing exchange schedule.

In its Reply to NRDC's Sur-Reply, EPA asserts that "EPA does not endorse the EBDC/ETU petition," and that the "only decision that EPA supports is its own determination that a hearing was warranted." April 4 Reply to Sur-Reply at 1, 2.

This Tribunal finds EPA's assertion at this point in the proceeding that it does not "endorse" the EBDC petition, disingenuous and difficult to reconcile with EPA's many prior statements clearly indicating the commonality of its position in this case with that of the Task Force. Such statements including the representation that the Task Force had presented to it "compelling justification for extending the 3-day PHI to all states;" that it "has determined" that the petition requesting a modification of the cancellation order "has merit;" that the "Agency believes it appropriate under this circumstance to modify the cancellation order to allow a 3-day PHI," (72 Fed. Reg. at 37771), that "[t]hrough the reregistration process, EPA determined that the exposure that would result from a nationwide 3-day PHI for potatoes would be safe under the

FFDCA reasonable certainty of no harm standard" (Motion at 20-21); and that "if no other interested party requests a hearing, the Agency intends to file a motion . . . requesting that the Administrative Law Judge issue an accelerated decision . . . in favor of modifying the cancellation order as requested" (72 Fed. Reg. at 37778). In fact, at no prior point in this proceeding had EPA ever asserted that its position as what it believed should be the appropriate outcome of this proceeding differed in any way from that of the Task Force. The Pre-Hearing Order directed the Task Force and EPA to file their initial pre-hearing exchanges first (before the NRDC) on or before the same date on the basis of the alignment of the parties' positions in this matter and efficiency of this proceeding. The Task Force has the burden of proof and is required under 40 C.F.R. § 164.132 to proceed first, EPA and the Task Force are both parties to this case, they appear to share the same position in this matter, they likely possess many of the same documents in support of the request to reduce the PHI to three days nationwide, and therefore they may either submit a joint pre-hearing exchange or EPA may consult with the Task Force and prepare a pre-hearing exchange which incorporates by reference documents which will be submitted by the Task Force. EPA's pre-hearing exchange is not a response or defense to NRDC's case, but EPA has an opportunity to submit a rebuttal to NRDC's pre-hearing exchange if it wishes.

Accordingly, EPA's request to modify the sequence of the pre-hearing exchange is denied.

ORDER

1. EPA's Motion for Clarification is **GRANTED** in part, to clarify that the hearing in this matter is to address the question of whether the PHI should be reduced nationwide to three days for potatoes, based on adjudication of the issues stated in 40 C.F.R. § 164.132(a), and that the outcome of this matter is a conclusion either that substantial new evidence exists that requires reversal or modification of the 1992 Order or that the earlier cancellation order must remain in effect and the application to reduce the PHI nationwide to three days may not be considered.

2. EPA's Motion for Clarification is **DENIED** as to the request to clarify that only dietary issues relevant to the dietary risks that formed the basis of the earlier cancellation order are relevant to this proceeding.

3. EPA's Motion for Reconsideration is **DENIED.**

4. EPA's request to adjust the sequence of the pre-hearing exchange to submit its pre-hearing exchange after the Task Force and NRDC exchange theirs, is **DENIED.**

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Susan L. Biro
Chief Administrative Law Judge

Dated: May 15, 2008
Washington, D.C.